



Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW Washington, DC 20204

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:
  Pharmavite Corporation, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
  Valerian root has been popular for centuries with people seeking natural support to enhance their nighttime rest. Unlike OTC sleep medications, Valerian root does not produce a hangover-like effect.
- (3) Name of the dietary ingredient if not provided in the text of the statement: see above
- (4) Name of the dietary supplement:
  products containing Valerian root as a single ingredient or in combination with
  other ingredients

The above statement(s) may be used in one or more of the following brands of products: Nature Made, Sunny Maid, Nature's Resource, AAFES, AARP, Osco, Sav-On, Valu Wise, Bartell Drug, CVS, Duane Reade, Walgreens, Longs, Spring Valley, Brite Life, Family Pharmacy, GNP, Valu-Rite.

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

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Acting Director, Regulatory and Consumer Affairs

LET 4912, 69031